DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 10/17/11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 6, 74-80, 82, 84, 86, 88, 90-95 and 97-108 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Masson et al (USPN 5,419,920 hereafter '920) and Cuca et al (USPN 5,494,681 hereafter '681).

The '920 patent discloses a method of imparting a scent or scent profile to an object and further detecting that scent at a later time (abstract). The scent is imparted at a level below that of the human olfactory sense, such that it is detectable by a non-human animal (col. 1, lin. 50-55). The scent is associated with the object or portion of the object and is used to authenticate the object in case of loss or theft. Further the authentication would allow for differentiation between authentic and counterfeit objects (col. 1, lin. 15-25). The scent is imparted to the object

during the manufacturing process (col. 4, lin. 23-31). The scent is absorbed into a substrate such as film, fiber or sponge, where the substrate is a polyolefin such as polyethylene (*Ibid.*).

What is lacking from the '920 reference is a disclosure of a specific dosage form and drug.

The combination of a scent to a dosage form comprising a drug is well known as seen in the '681 patent. The '681 patent discloses a tasteless drug dosage form comprising opioids such as codeine and morphine (col. 3, lin. 29-31). The dosage form can be a capsule (col. 6, lin. 55-65). The dosage form comprises essential oils and synthetic oils such as peppermint, spearmint, and fruit oils such as orange, lemon and grape (col. 7, lin. 1-15). It would have been obvious to track and identify the dosage form of the '681 patent by the method of the '920 patent in order to keep track of schedule I or II substances from a distance. It is further noted that the instant claims do not recite an active step of "authenticating" the dosage form, but only "allowing" for the dosage form to be authenticated. Clearly providing a dosage form with a scent, such as orange, etc. in the '681 patent would "allow" (render capable) the dosage form to be authenticated via smell, thus meeting the allowing step recited in the instant claims.

Regarding the manufacturing information limitation in the claims, it is the position of the Examiner that these limitations do not distinguish the claims over the prior art. The specific flavors of the '681 patent would indicate that the manufacturing process involved confectionary oils and that the dosage form was manufactured in the presence of confectionary materials. The flavors/scents would indicate that the manufacturing facility had access to confectionary materials as well as schedule I opioids, limiting the source of the dosage form. This information would meet the limitations of the instant claims.

Regarding the differentiation between batches, it would be obvious to apply different flavors to different batches in order to tell them apart after manufacture. Varying the scent profile with different batches would allow the artisan of ordinary skill to tell the difference between codeine, morphine and other opioid analgesics.

With these things in mind it would have been obvious to combine the prior art in order to detect and track drug compositions from a distance. The '920 patent establishes the level of skill in the art regarding imparting a traceable scent to a polymeric film. These scented polymeric forms can be found in drug dosage forms as seen in the '681 patent. It would have been obvious to tract the scented dosage forms of the '681 patent by the method of the '920 patent in order to prevent theft and reduce counterfeiting. Additionally, the '681 patent alone meets the limitations of "allowing for an authentication of the dosage form" by merely adding the scent, as explained above.

Response to Arguments

Applicant's arguments filed 10/17/11 have been fully considered but they are not persuasive. Applicant argues that the prior art does not obviate the instant claims and that the functional limitations are only met through impermissible hindsight reconstruction and reliance on the instant specification.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the instant case the instant claims are drawn to a method comprising a single active step, specifically imparting a scent to an object. The '920 patent clearly discloses the imparting of a scent or scent profile to an object including a polymeric film. The intent of the patent is to apply a tracking and identification means to an object that is subject to theft and that can be authenticated upon retrieval or receipt. The scents applied are below the human olfactory sense and within the range of canine and non-canine animals. The animal can be trained to distinguish complex scent profiles and aid in authentication (col. 3, lin. 15-40). Regarding labeling the scent increased or decreased based on the material and purpose of the object (variation between batches). (col. 4, lin. 10-20). The reference is silent to a specific pharmaceutical dosage form, however polymeric films are suggested and overall objects and items that are more likely to be stolen or counterfeit are envisioned by the '920 patent as being useful for labeling. With this in mind it would have been obvious to combine these disclosures with opioid dosage forms of '681. The '681 patent comprises schedule II opioids that require verification and control by government agencies and regulators. It would be obvious to impart scent profiles onto these dosage forms in order to more tightly control their distribution and recovery if ever stolen.

It remains the position of the Examiner that the instant claims are obviated by the prior art. The instant claims are drawn to a method of identifying a pharmaceutical dosage form, comprising a single active step, specifically imparting a scent to eh dosage form. The remains functional limitations are all gleaned from the imparting of the scent profile. Allowing for the scent to be authenticated is not an active step in any meaningful way in that "allowing" of the scent to be verified contains no active steps and can be accomplished by simple detection. Further this authentication even if taken as an active step is fully disclosed by the '920 patent. The variation in batch concentration is also covered by the '920 patent. The manufacturing information limitation is broad and can be accomplished by simple detection. By detecting the scent using an animal, there has been an indication that the dosage form was manufactured or bottled in a plant or manufacturing facility with access to or in possessing of a scent dispensing device. This would indicate where the dosage form was manufactured, meeting the limitation of the claims. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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